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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,983	02/28/2001	Tom Gilchrist	MUR-8564US	3635

7590

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EXAMINER
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WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/763,983

Applicant(s)

GILCHRIST ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,11 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,11 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-5, 7-8, 11 and 22-26 are pending. The Amendment filed 1/7/03, Paper No.8, cancelled claims 6, 9, 10, 12-21 and amended claims 1-5, 7, 8, 11 and 22-24.

#### ***Response to Arguments and 132 Declaration***

Applicant's arguments with respect to claims 1-5, 7-8, 11 and 22-26 have been considered but are moot in view of the new ground(s) of rejection, as necessitated by Applicant's amendments to the claims filed 1/7/03, Paper No. 8.

Regarding the declaration, the Examiner respectfully points out that it is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, Applicant's declaration is not persuasive. First, the declaration is not commensurate in scope with the instant claims. The instant claims recite a precipitant selected from calcium citrate or calcium releasing water soluble glass and the instant declaration is only directed toward foams comprising calcium citrate. Furthermore, the primary reference, Gilchrist et al., is directed toward foams comprising calcium releasing water soluble glass and teaches that their foams can be sterilized by gamma irradiation.

Additionally, the Examiner respectfully points out that on page 11 of Gilchrist et al. it is disclosed that calcium released from the glass will stabilize the alginate by forming the insoluble calcium salt. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to experiment with different concentrations of calcium salt to obtain the most stable alginate foam.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-8, 11, 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claim 1 is vague and indefinite, as it is confusing. Are steps “b)” and “d)” referring to two different steps in which the foam and the precipitant are combined?

(ii) Claim 2 is vague and indefinite, as it is confusing. How can the precipitant and gelling agent be packaged separately and still be immersed in a bath, dried, and sterilized via gamma irradiation or ethylene oxide?

(iii) Claim 3 is vague and indefinite, as it is confusing. Is Applicant claiming a range within a range? Are not alginate, carageenans, and others polysaccharides? Is glycol metacrylate incorrectly spelled? Should the claim recite glycol methacrylate?

(iv) Claim 4 is vague and indefinite, as it is confusing. Is Applicant intending only to claim salts of carboxymethyl-cellulose or should the claim recite, “salts thereof” instead of “salt thereof”.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 7-8, 11 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilchrist et al. (WO 96/17595).

Gilchrist et al. teach foamable formulations and foams. Alginate, carboxymethylcellulose, collagen, polysaccharide, agar, and others are taught as foamable carriers in the formulations, wherein the carriers having a MW from 10,000-200,000kDa. Cetrimide, lecithin, soaps, and silicones are taught as foaming agents. Acetic acid is taught as an antiseptic/antibacterial/antifungal agent that can be added to the formulation. A method of making the foams is taught, wherein the foams are produced on a suitable surface and then dried, and wherein foam formulations are sterilized via gamma radiation. Metal ions, such as calcium ions, are introduced into the formulations via a glass composition, wherein the glass is admixed with the formulation during the foaming process. The reference lacks an exemplification of the instant method. See pg. 5, line 15-pg. 6, line 12; pg. 8, line 4-pg. 9, line 16; pg. 10, lines 4-17; pg. 11, lines 7-12; pg. 12, lines 7-31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the instant method using the teachings of Gilchrist et al. because Gilchrist et al. teach combining gelling agent and precipitant, such as calcium releasing water soluble glass, and drying the product and further teaches that production will generally take place

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under sterile conditions; thus, one of skill would be motivated to exemplify the process of Gilchrist wherein the calcium releasing water soluble glass is the precipitant and the formulation is sterilized by gamma irradiation because of the expectation of achieving a very stable gel that is free of agents that would be harmful in medical or veterinary use, such as microbes.

While the amount of the organic acid to the gelling agent is not specifically disclosed, the Examiner respectfully points out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

While the reference does not teach immersing the foam in a bath of precipitate, it does teach combining the foam with the precipitate. Thus, whether this combination occurs in a bath or other medium is not relevant.

Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilchrist et al. as applied to claims 1, 3-5, 7-8, 11 and 26 above, and further in view of Eagles et al. (WO 94/00512).

Gilchrist is applied as discussed above. The reference lacks a washing step.

Eagles et al. teach a method of producing polysaccharide foams comprising alginate, hyaluronate, carrageenan, or chitosan. The foams are air dried after formation to form a collapsed foam. After drying the foam may be washed with water and the redried to remove any foaming agent or foam stabilizer residual in the foam. See pgs. 10, 12, 14, 16-17, 21-22.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the washing steps of Eagles et al. into the process of Gilchrist et al. because of

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the expectation of achieving a polysaccharide foam product that is free of residual foaming agent and foaming stabilizer.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilchrist et al. in view of Eagles et al. as applied to claims 1, 3-5, 7-8, 11 and 25-26 above, and further in view of Kobayashi et al. (5,641,450).

Gilchrist et al. and Eagles et al. are applied as discussed above. The references lack a glycerine wash.

Kobayashi et al. teach a process of making a module including a polysulphonic hollow fiber membrane. A water/glycerine wash is taught as a means preventing drying and hence deterioration of a product prior to being cut to a predetermined length. See Col. 4, lines 3-11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add glycerine to the water wash of the combined references because of the expectation of achieving a foam product that does not deteriorate upon cutting.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilchrist et al. in view of Eagles et al. as applied to claims 1, 3-5, 7-8, 11 and 25-26 above, and further in view of Krzysik et al. (6,204,208).

Gilchrist et al. and Eagles et al. are applied as discussed above. The reference lacks oven-drying.

Krzysik et al. teach a method and composition for treating substrates for wettability and skin wellness. Exemplified is a foam that was oven dried at 60 C for 30 minutes. See Col. 21, lines 35-45.

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Kehr et al. teach a dimensionally stable polyurethane foam. The foams were microwave dried, vacuum oven dried, and then air dried for 2 days. See Col. 9, line 20-Col. 10, line 12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add oven drying to the drying step of the combined references because of the expectation of achieving enhanced moisture evaporation and hence, stability of the foam.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilchrist et al. as applied to claims 1, 3-5, 7-8, 11 and 25-26 above, and further in view of Clare et al. (4,693,728)

Gilchrist et al. is applied as discussed above. The reference lacks calcium citrate.

Clare et al. teach hydrocolloid blend for controlled release of calcium ions. The reference teaches that the introduction of divalent ions into soluble alginate solutions rapidly causes gelation through the formation of mixed alginate salts. Where it is desirable to control the speed of this gelation, various methods have been proposed, such as combining calcium citrate with soluble alginated to produce calcium ions that are released over time. See Col. 1, lines 5-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute calcium citrate for the calcium ion glass composition of the combined references because calcium citrate and calcium ion glass compositions are equivalent in their effect of slowly releasing metal ions from foams, and because of the expectation of achieving a method wherein lower concentrations of alginate are used to generate a given viscosity.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
February 24, 2003



SREENI PADMANABHAN  
PRIMARY EXAMINER

2/24/03